Where can I go for updates and more information? The most up-to-date information on COVID-19 is available at the CDC General webpage: https://www.cdc.gov/COVID19. In addition, please also contact your healthcare provider with any questions/concerns.

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

What is the BinaxNOW COVID-19 Ag Card?
The BinaxNOW COVID-19 Ag Card is a type of test called an antigen test. Antigen tests are designed to detect proteins from the virus that causes COVID-19 in respiratory specimens, for example nasal swabs.

What are the known and potential risks and benefits of the test?
Potential risks include:
- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:
- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

What does it mean if I have a positive test result?
If you have a positive test result, it is very likely that you have COVID-19. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false positive result). Your healthcare provider will work with you to determine how best to care for you based on your test result(s) along with your medical history, and your symptoms.

What does it mean if I have a negative test result?
A negative test result means that proteins from the virus that causes COVID-19 were not found in your sample. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. If your test result is negative, your healthcare provider will consider the test result together with
all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. The amount of antigen in a sample may decrease the longer you have symptoms of infection. Specimens collected after you have had symptoms for more than seven days may be more likely to be negative compared to a molecular assay.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

**What are the differences between antigen tests and other COVID-19 tests?**

There are different kinds of tests for COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests detect proteins from the virus. Antigen tests are very specific for the virus, but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection.

If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test would help with your care, and when you should discontinue home isolation. If you will not have an additional test to determine if you are contagious, the CDC currently recommends that you stay home until three things have happened:

- You have had no fever for at least 24 hours (that is one full day of no fever without the use of medicine that reduces fevers)

**AND**

- Other symptoms of COVID-19 are improving **Loss of taste and smell may persist for weeks or months after recovery and need not delay the end of isolation**

**AND**

- At least 10 days have passed since your symptoms first appeared.

For more information, the CDC has provided guidelines on how to prevent the spread of COVID-19 if you are sick: https://www.cdc.gov/coronavirus/2019-ncov/downloads/sick-with-2019-nCoV-fact-sheet.pdf

**Is this test FDA-approved or cleared?**

No. This test is not yet approved or cleared by the United States FDA. FDA may issue an Emergency Use Authorization (EUA) when certain criteria are met, which includes that there are no adequate, approved, available alternatives. The EUA for this test is supported by the Secretary of Health and Human Service’s (HHS’s) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

**What are the approved alternatives?**

There are no approved available antigen alternative tests. Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: https://www.fda.gov/medicaldevices/device-advice-comprehensive-regulatoryassistance/medical-device-databases.

A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policyframework/emergency-use-authorization.

TB000043 Rev. 3

© 2021 Abbott. All rights reserved. All trademarks referenced are trademarks of either the Abbott group of companies or their respective owners.